01-07-08 IFW 1648

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Barbara Ensoli	Confirmation No.:	9400
Application No.:	09/555,534	Art Unit:	1648
Filed:	May 31, 2000	Examiner:	Humphrey, Louise Wang Zhiying
For:	HIV TAT, OR DERIVATIVES THEREOF FOR PROPHYLACTIC AND THERAPEUTIC VACCINATION	Attorney Docket No.:	11340-003-999

STATEMENT OF SUBSTANCE OF INTERVIEW UNDER 37 C.F.R. § 1.133

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.133 and MPEP 713.04, Applicant submits this Statement of Substance of Interview in connection with the personal interview on December 5, 2007 between Examiner Zack Lucas, Examiner Louise Wang Humphrey, and Applicant's representatives Dr. Adriane Antler and Ms. Ann Chen, and, participating by telephone, the Inventor Dr. Barbara Ensoli, and Dr. Giovanni Cozzone, Dr. Paolo Monini, and Prof. Mauro Magnani, in connection with the above-identified application.

INTERVIEW SUMMARY

First, Dr. Antler addressed the enablement rejection under 35 U.S.C. § 112, first paragraph, and explained that the claimed composition is enabled, for reasons essentially as set forth in the Amendment Under 37 C.F.R. § 1.114 filed October 22, 2007. In particular, Dr. Antler explained that one patentable utility needs to be enabled to satisfy the enablement requirement and Applicant has demonstrated, by means of the Second Declaration of Barbara Ensoli, M.D., Ph.D. Under 37 C.F.R. § 1.132 ("Second Ensoli Declaration") filed May 1, 2007, multiple enabled uses of the claimed composition, including uses to generate an immune response and/or treatment of HIV infection. Dr. Antler also explained that while the specification indicates the use of PMSF or HPLC in the procedure for preparation of a

biologically active Tat protein, a person skilled in the art, based on the teaching of the specification and common knowledge at the time of invention, could avoid the use of PMSF and/or HPLC that uses the acetonitrile/TFA solvent system to obtain a Tat composition that is pharmaceutically acceptable for administration to a human without undue experimentation, as demonstrated by the Declaration of Mauro Magnani, Ph.D. Under 37 C.F.R. § 1.132 ("First Magnani Declaration") filed May 1, 2007 and the Supplemental Declaration of Mauro Magnani, Ph.D. Under 37 C.F.R. § 1.132 ("Supplemental Magnani Declaration") filed November 22, 2007. In response, Examiner Humphrey indicated that she was not aware of the submission of the Second Ensoli Declaration, First Magnani Declaration and Supplemental Magnani Declaration, and would reconsider the outstanding rejections in view of these declarations.

Subsequently, Dr. Antler addressed the anticipation rejection under 35 U.S.C. § 102, and explained that Chang *et al.* (AIDS. 1997 Oct;11(12):1421-31, "Chang") neither explicitly nor inherently discloses the claimed composition, for reasons essentially as set forth in the Amendment Under 37 C.F.R. § 1.114 filed October 22, 2007. Finally, Dr. Antler addressed the obviousness rejection under 35 U.S.C. § 103, and explained that there is no motivation in Chang or any of the other cited references to modify the purification methods of Chang so that PMSF and other components that are not pharmaceutically acceptable for administration to a human are avoided, especially in view of the prejudice in the art against administering biologically active Tat to humans.

FURTHER REMARKS

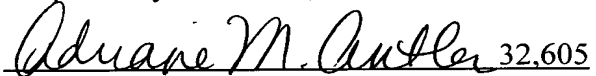
Furthermore, Applicant wishes to correct for the record certain inaccurate statements in the Interview Summary dated December 7, 2007. In particular, Dr. Antler did not state during the interview that "the specification discloses nothing other than a vaccine" (see Interview Summary, Continuation Sheet, line 6). In addition, Dr. Antler did not state during the interview that "it is routine practice in the art to remove toxins [PMSF, TFA and acetonitrile] after protein purification" (see Interview Summary, Continuation Sheet, lines 11-12). Instead, Dr. Antler stated during the interview that a person skilled in the art could *avoid using* such toxins in purifying Tat using knowledge common (routine practice) in the art. However, Dr. Antler emphasized that the person skilled in the art would not have reason to administer the biologically active Tat taught by Chang to humans and thus to avoid the toxins during purification, in view of the prejudice in the art against administering biologically

active Tat. Moreover, in traversing the rejections under 35 U.S.C. §§ 102 and 103, Dr. Antler explained that Chang does not teach any common sense reason to avoid using the toxins in Tat protein purification.

Applicant respectfully requests entry of the foregoing remarks into the file history of the above-identified application. It is believed that no fee is due in connection with this submission. However, in the event any fee is required, please charge the required fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

Date: January 4, 2008



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